



Product Service

CERTIFICATE

No. Q4N 16 04 59145 005

Holder of Certificate: **Goals Sterilization Co., Ltd.**

East of Renkangtang
 South of 07 provincial road, Xinfeng Town
 Nanhu District
 314005 Jiaxing, Zhejiang
 PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Goals Sterilization Co., Ltd.
 East of Renkangtang, South of 07 provincial
 road, Xinfeng Town, Nanhu District, 314005
 Jiaxing, Zhejiang, PEOPLE'S REPUBLIC OF
 CHINA



Certification Mark:



Scope of Certificate: **Provision of ETO Sterilization Service for Single-Used Medical Device**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012

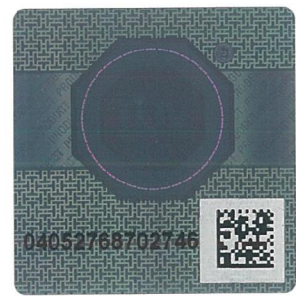
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1646511

Valid from: 2016-06-30
Valid until: 2018-03-31

Date, 2016-06-29

S. Preis
 Stefan Preis





Product Service

Supplement to Quality System Certificate Q4N.16.04.59145.005

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2016-06-29 to

Goals Sterilization Co., Ltd.

East of Renkangtang
South of 07 provincial road, Xinfeng Town
Nanhu District
314005, Jiaxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

for the facility

Goals Sterilization Co., Ltd.

East of Renkangtang
South of 07 provincial road, Xinfeng Town
Nanhu District
314005, Jiaxing, Zhejiang
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The quality system certified as stated above additionally fulfills the applicable requirements of **EN ISO 11135-1: 2007 - Sterilization of health care products - Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** - as documented in the audit report no. SH1646511 dated 2016-04-29.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

TÜV SÜD PRODUCT SERVICE GMBH
Certification Committee for Medical Devices

Stefan Preiß

Munich, 2016-06-29

TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.

